REMARKS

Consideration and entry of this paper, and reconsideration and withdrawal of the rejections of the pending claims are respectfully requested in view of the amendments and remarks herein, which place the application in condition for allowance, or in better condition for appeal.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1-63 are pending in this application. Claims 3-5, 8, 9, 11-13, 15, 16 and 18-63 were withdrawn from further consideration. Claims 1 and 2 have been amended to correct typographical errors. In addition, claim 1 has been amended to recite a crystallization inhibitor system comprising a polymeric film-forming agent and a surfactant. Claim 10 has been amended to depend from claim 6.

Support for the amended claims can be found throughout the specification as filed (see, for example, paragraphs 0640-0647 and Example 2 of the application as published).

No new matter has been added.

Applicants thank the Examiner for withdrawing the rejections of the claims under 35 U.S.C. § 103(a) as being obvious over Meinke et al.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited in the Office Action, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. It is submitted that the amendments of the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled.

The issues raised by the Examiner in the Office Action are addressed below in the order they appear in the prior Action.

II. THE REJECTIONS UNDER 35 U.S.C. §102 ARE OVERCOME

Claims 1, 2, and 6 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Meinke et al. (WO9629073) and Cleverly (USAN 2004/0037869). Applicants respectfully traverse in view of the claims as amended. The cited references do not anticipate the pending claims.

The Examiner alleges that Meinke teaches a formulation comprising the elected t-butyl nodulisporamide and the liquid carriers such as propylene glycol and that the formulation can be a spot-on formulation.

It is respectfully pointed out that a two-prong inquiry must be satisfied in order for a Section 102 rejection to stand. First, the prior art reference must contain all of the elements of the claimed invention. *See Lewmar Marine Inc. v. Barient Inc.,* 3 U .S.P.Q.2d 1766 (Fed. Cir. 1987). Second, the prior art must contain an enabling disclosure. *See Chester v. Miller,* 15 U.S.P.Q.2d 1333, 1336 (Fed. Cir. 1990). A reference contains an enabling disclosure if a person of ordinary skill in the art could have combined the description of the invention in the prior art reference with his own knowledge of the art to have placed himself in possession of the invention. *See In re Donohue*, 226, U.S.P.Q. 619, 621 (Fed. Cir. 1985).

Meinke does not teach or suggest a crystallization inhibitor in a spot-on formulation. As such, Meinke does not teach or suggest all elements of the instant claims.

The Examiner rejects claims 1, 2, and 6 under 35 U.S.C. § 102(b) over Cleverly. However the Examiner does not state any reasons why he contends Cleverly anticipates the pending claims. Clarification is requested.

Nonetheless, Cleverly does not teach or suggest a crystallization inhibitor system comprising a film-forming agent and a surfactant in a spot-on formulation. Cleverly relates to oral formulations and does not teach or suggest spot-on formulations comprising nodulisporic acid derivatives. Moreover, contrary to the Examiner's assertion, Cleverly pertains to benzyl alcohol as a preservative and not as a crystallization inhibitor in a formulation. Cleverly relates to various crystallization inhibitors only as possible surfactants for oral formulations, not spot-on formulations as recited in the instant claims.

The Examiner asserts that "whether the formulation is spot on or an oral formulation does not matter since a statement of intended use in a claim to a formulation does not carry patentable significance" (Office Action, page 3).

The Examiner is respectfully reminded that all words in the claims must be considered in evaluating the patentability of the claims over the prior art. *In re Wilson*, 165; *see also In re Swinehart*, 169 U.S.P.Q. 227 (C.C.P.A. 1971) ("point of novelty" was "transparen[cy]"; Court held that "functional" or "use" language was permissible, even at the "point of novelty" indicating that "there is nothing intrinsically wrong" with claiming by what something does); *In*

re Duva, 156 U.S.P.Q. 90 (C.C.P.A. 1967) (prior art rejection of aqueous solution "for depositing gold" reversed due to PTO failure to consider the "for depositing gold" recitation because "all factual differences which may be properly noted in any portion of a claim must be included within the basis for comparison with the prior art if we are to properly evaluate the difference between the invention defined in a claim and the teachings of a reference", i.e., "every portion of the ... claims must be considered"). For instance, it is well-established law that where the preamble is essential to point out the claimed invention and give meaning and vitality to the claim, it is given the effect of a limitation. *See, e.g., Diversitech Corp. v. Century Steps Inc.*, 850 F.2d 675, 7 U.S.P.Q.2d 1315 (Fed. Cir. 1988); *In re Tuominen*, 671, F.2d 1359, 213 U.S.P.Q. 89 (C.C.P.A. 1982); *In re Bulloch et al.*, 604 F.2d 1362, 203 U.S.P.Q. 171 (C.C.P.A. 1979); *In re Szajna et al.*, 422 F.2d 443, 164 U.S.P.Q. 632 (C.C.P.A. 1970); *In re Walles et al.*, 366 F.2d 786, 151 U.S.P.Q. 185 (C.C.P.A. 1966); *Smith v. Bousquet*; 111 F.2d 157, 45 U.S.P.Q. 347 (C.C.P.A. 1940); *Ex parte Varga*, 189 U.S.P.Q. 204 (P.O.B.A. 1973); *see also Kropa v. Robie et al.*, 187 F.2d 150, 88 U.S.P.Q. 478 (C.C.P.A. 1951).

Clearly, the term "spot-on" patentably distinguishes the claimed invention from the documents cited by the Examiner, and provides that the claimed invention is not encompassed by the art cited in the Office Action.

Secondly, Meinke and Cleverly do not enable Applicant's invention, which provides a spot-on formulation comprising nodulisporic acid derivatives. It appears that the Examiner attempts to improperly extrapolate the teachings of Meinke and Cleverly to arrive at the instant invention.

Contrary to the Examiner's assertion, it is not possible to extrapolate results from oral formulations to spot-on formulations of the instant invention. It is well known in the art that oral formulations are not the same as spot-on formulations.

As mentioned earlier, neither Meinke nor Cleverly teach or suggest a crystallization inhibitor system comprising a film-forming agent and a surfactant in a spot-on formulation.

For the foregoing reasons, the cited references do not anticipate the instant claims. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 102 are respectfully requested.

III. THE REJECTIONS UNDER 35 U.S.C. §103 ARE OVERCOME

Claims 1, 2, 6, 7, 10, 14, and 17 are rejected under 35 U.S.C. § 103(a) as being obvious over Meinke et al (WO9629073) and Cleverly (USAN 2004/0037869). Applicants respectfully traverse in view of the claims as amended. The cited references do not render the pending claims obvious.

The Examiner asserts that Meinke teaches a formulation comprising the elected t-butyl nodulisporamide and the liquid carriers such as propylene glycol and that the formulation can be a spot-on formulation. The Examiner also alleges that Cleverly teaches a formulation that can contain numerous pharmaceutical agents including nodulisporic acid derivatives and can be a pour-on formulation. The Examiner further alleges that Cleverly teaches that a formulation can comprise benzyl alcohol and /or polyoxyethylene sorbitan fatty acid ester as crystallization inhibitors. The Examiner concludes that it would have been obvious to one having ordinary skill in the art to combine the cited references to arrive at a formulation as claimed.

Establishing a *prima facie* case of obviousness requires that the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143.

The Examiner is respectfully reminded of the case law, namely, that there must be some prior art teaching which would have provided the necessary incentive or motivation for modifying the reference teachings. *In re Laskowski*, 12 U.S.P.Q. 2d 1397, 1399 (Fed. Cir. 1989); *In re Obukowitz*, 27 U.S.P.Q. 2d 1063 (BOPAI 1993). As stated by the Court in *In re Fritch*, 23 U.S.P.Q. 2d 1780, 1783-1784 (Fed. Cir. 1992): "The mere fact that the prior art may be modified in the manner suggested by the Office Action does not make the modification obvious unless the prior art suggests the desirability of the modification." Also, the Examiner is respectfully reminded that for the Section 103 rejection to be proper, both the suggestion of the claimed invention and the expectation of success must be founded in the prior art, and not Applicants' disclosure. *In re Dow*, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Furthermore, the Supreme Court has recently reaffirmed the factors set out in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18: "[T]he scope and content of the prior art are determined; differences between the prior art and the claims at issue are...ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances

surrounding the origin of the subject matter sought to be patented." *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___ (2007).

Cleverly relates to oral veterinary formulations and does not teach or suggest spot-on formulations comprising nodulisporic acid derivatives. Moreover, contrary to the Examiner's assertion, Cleverly pertains to benzyl alcohol as a preservative and not as a crystallization inhibitor in a formulation. Cleverly relates to various crystallization inhibitors only as possible surfactants for oral formulations, not spot-on formulations as recited in the instant claims.

Meinke does not teach or suggest any spot-on formulations comprising nodulisporic acid derivatives and propylene glycol. Meinke mentions spot-on formulations only very generally as a possible way of applying an active compound to humans and animals to control internal or external parasites (page 34, line 15-21) but does not specify any compositions or possible ingredients of such formulations.

Moreover, Meinke relates to propylene glycol as a possible vehicle for parenteral administration (page 35, line 24-29) but not as a vehicle for a spot-on formulation.

Further, Meinke does not teach or suggest a crystallization inhibitor in a spot-on formulation. Neither Meinke nor Cleverly teach or suggest a crystallization inhibitor system comprising a film-forming agent and a surfactant in a spot-on formulation.

For the foregoing reasons, the references cited by the Examiner, either alone or in combination, do not render the claimed subject matter *prima facie* obvious. Accordingly, reconsideration and withdrawal of the rejections under 35 U.S.C. § 103(a) are respectfully requested.

REQUEST FOR INTERVIEW

If any issue remains as an impediment to allowance, an interview with the Examiner and SPE is respectfully requested; and, the Examiner is additionally requested to contact the undersigned to arrange a mutually convenient time and manner for such an interview.

CONCLUSION

For the reasons stated above, Applicants respectfully request a favorable reconsideration of the application, consideration and entry of this paper, reconsideration and withdrawal of the rejections of the pending claims, and prompt issuance of a Notice of Allowance.

Respectfully submitted,
MERIAL LTD.
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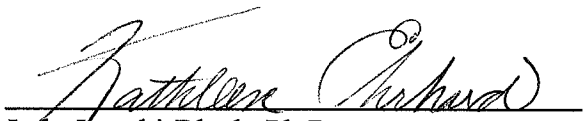
By: 

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